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Chairman Nelson, Ranking Member Collins, and Members of the Committee, thank you for inviting me to testify on the Medicare prescription drug program, also known as Part D.

**Drug Discovery and Better Health**

PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. The Congressional Budget Office (CBO) reports that the pharmaceutical sector is one of the most research-intensive industries in the United States, investing as much as five times more in research and development than the average U.S. manufacturing firm.[i] According to the National Science Foundation, biopharmaceutical companies account for about $1 out of every $5 of industry research and development (R&D) undertaken in the U.S.[ii] Since 2000, PhRMA member companies have invested approximately $550 billion in the search for new treatments and cures for disease.[iii]

This investment in the discovery and development of new medicines has produced numerous medical advances that have changed the course of disease and the face of medical care. The breadth and scope of these advances is far too great to comprehensively describe. A few examples follow of the dramatic impact medicines have made in the fight against cancer, cardiovascular disease, HIV/AIDs, and hepatitis C:

- Since 1988, life expectancy for cancer patients has increased about 4 years, with roughly 80% of those gains attributable to new treatments, including medicines.[iv] Increases in life expectancy for cancer patients between 1988 and 2000 yielded 23 million additional life years and roughly $1.9 trillion of additional social value, four-fifths of which accrued to patients.[v] Further, between 2000 and 2011, cancer deaths have fallen by 15.5%.[vi] These medical advances have a profound impact on seniors, who account for more than half of all new cancer cases.[vii]

- Cardiovascular disease represents a significant disease burden today; an estimated 82.6 million adults are living with one or more types of cardiovascular disease, and the prevalence of heart disease is nearly three times higher in seniors compared to other age groups.[viii] However, due to the benefits of biomedical innovation, the death rate for cardiovascular disease fell 33% just between 1999 and 2009.[ix] In the words of researchers at Johns Hopkins University, "protein enzymes, receptors, or channels identified by the pharmaceutical industry as 'drugable targets' have led to striking, remarkable, and repeated achievement."[x] Leading researchers estimate that just one class of cardiovascular medicines – statins – yielded about 40,000 fewer deaths and 82,000 fewer hospitalizations for heart attack and stroke in 2008. Harvard researcher David Cutler has found that "Reduced disability associated with cardiovascular disease accounts for a significant part of the total reduction in disability [among community dwelling Medicare recipients]—between 19 and 22 percent. The evidence suggests that improvements in medical care, including both increased use of relevant procedures and pharmaceuticals, led to a significant part of this decline."[xi]

- In today's world, an HIV/AIDs diagnosis is no longer considered a death sentence. Since the approval of antiretroviral treatments in 1995, the HIV/AIDS death rate has dropped by 85%.[xii] According to leading HIV researchers, "In stark contrast to the early and mid-1980s, if a person aged 20 years is newly infected with HIV today and guideline recommended therapy is initiated, researchers can predict by using mathematical modeling that this person will live at least an additional 50 years — that is, a close-to-normal life expectancy."[xiii]

- The treatment of hepatitis C is another important example of how new medicines can profoundly change the course of a disease that affects several million Americans and tens of millions around the globe. The chance that a patient would reach the goal of sustained virologic response (undetectable virus for 24 weeks after treatment) was about 10% in the 1990s and, with new medicines, improved to about 40% in the early- to mid-2000s. Two years ago, the introduction of protease inhibitors and triple therapy regimens revolutionized treatment for hepatitis C, increasing sustained virologic response to about 75%, depending on prior treatment experience.[xiv] [xv] These treatment advances are expected to halt the progression to end stage liver disease, reduce the need for liver transplantation, and prevent complications such as hepatocellular cancer, which will likely result in fewer deaths from the virus and avoided health care costs. Continuing innovation in hepatitis C treatments include new therapies on the horizon that have the potential to be even more efficacious, have improved safety profiles and be more convenient for patient use.

**The U. S. Biopharmaceutical Research Sector and the Economy**

The U.S. biopharmaceutical research sector leads the world in the development of new medicines, with more than 3,200 medicines in development or FDA review in the U.S. According to a 2011 Battelle study supported by PhRMA, the sector generates high-quality jobs and powers economic output and exports for the U.S. economy, serving as the "the foundation upon which one of the U.S.' most dynamic innovation and business ecosystems is built."[xvi] These jobs encompass the research-based occupations that will help sustain future U.S. economic growth, often requiring specialized science, technology, engineering, and math (STEM) skills. The U.S. biopharmaceutical sector directly provides more than 650,000 jobs, but supports a total of 4 million jobs across the economy. In 2009, the biopharmaceutical sector contributed $917 billion to the economy when considering direct, induced, and indirect effects.[xvii]

These economic impacts are driven by the R&D enterprise, in which PhRMA member companies alone invested an estimated $48.5 billion in 2012,[xviii] with most of these investments made in the U.S. The pharmaceutical sector was responsible for almost 20% of all U.S. business-funded R&D investment in 2008, a larger share than any other industrial subsector, with biopharmaceutical spending nearly twice as much on R&D as the automotive and aerospace industries combined.[xix] Biopharmaceutical companies invest more than ten times the amount of R&D per manufacturing job compared to manufacturing industries overall.[xx]

The President's Council of Advisors on Science and Technology recognized that the "nation's leadership in biomedical innovation has been supported by a robust industry, and, in turn, investments in biomedical research and corresponding medical advances have allowed industry and the economy to thrive. Biomedical innovation has supported U.S. economic growth, and high-value, high-skilled jobs for Americans."[xxi]

This sector, which drives science, medical advances and high quality jobs (with its R&D intensity driving its high multiplier effect on jobs throughout the economy), was not always centered in the U.S. Thirty years ago, Europe produced more than half of the intellectual property related to new medical compounds. Now, Europe represents roughly a quarter while the U.S. accounts for more than half.[xxii] Over the same timeframe the number of new drug approvals which were U.S. in origin increased while the percentage that were European in origin remained static. According to Günter Verheugen, formerly Vice-President of the European Commission responsible for Enterprise and Industry, Europe's loss of leadership in R&D in life sciences to the U.S. was due in part to the lack of a predictable and stable regulatory system and other policies that did not favor innovation.[xxiii]

The U.S. is recognized as the global leader in biopharmaceutical R&D. Burrill and Company reports that U.S. health biotechnology companies account for 80% of global health biotechnology R&D.[xxiv] A large part of the economy is built upon a robust foundation of

innovative biopharmaceutical companies that perform and support advanced R&D, and act as a funnel and distribution engine for getting life-saving and quality-of-life sustaining medicines to patients. To sustain this innovation requires a supportive policy environment.

**Trends in Spending for Prescription Medicines; Opportunities for Savings**

At the same time that medicines have been making extraordinary progress against disease, they account for a small share of health spending. For instance, an analysis by Avalere Health projects that between 2011 and 2019, brand medicines will account for approximately 8% of federal spending on Medicare and Medicaid.[xxv]

In addition to medicines' low share of overall health spending, growth in spending on medicines has slowed dramatically over the last decade. Recently, IMS Health reported that after years of historically low growth (averaging 3.4% annually for the past five years), spending on prescription medicines declined in both absolute terms and on a per capita basis in 2012.[xxvi] As IMS states, "The 'cost curve' for medicines—if not for other elements of the U.S. healthcare system—was bent."[xxvii] Spending on brand medicines alone decreased by 5%. IMS projects that future growth in prescription drug spending will remain at historically low levels, averaging 1% to 4% between 2012 and 2016.[xxviii]

Historical data from the Center for Medicare & Medicaid Services' Office of the Actuary (OACT) paints a similar picture. OACT's most recent data show that retail prescription drug spending grew by 0.4% in 2010 and 2.9% in 2011, while overall health spending grew by 3.9% in both years. Notably, four of the five lowest growth rates in spending on medicines OACT has reported over the past 50 years have occurred since 2006, the year Part D was implemented.

The trends in prescription medicine spending are the result of many factors, including several that are unique to the biopharmaceutical sector. Medicines are mostly purchased in a national market by very large, powerful, sophisticated purchasers who specialize in buying medicines and making aggressive use of various tools to achieve savings, driving utilization to the medicines for which they can negotiate the lowest prices.

Related to all of these factors is the prescription medicine lifecycle. In this lifecycle, innovator pharmaceutical companies produce medical advances through pioneering scientific work and large-scale investments, leading over time to generic copies that patients use at low cost for many years. Savings from generics are possible only because the medicine was previously invented by an innovator company, and the marketplace is quick to take up use of generics when they become available. This process provides built-in cost containment not available in other health sectors by continuously freeing up resources and reallocating spending from older to newer medicines. Although savings from the market's aggressive leveraging of the prescription medicine lifecycle are often ignored in policy debates discussing cost savings, the lifecycle is a

central characteristic of the market for prescription medicines. Today, generic drugs account for 84% of all prescriptions filled in the U.S.[xxix].

While prescription medicines are typically singled out and treated as a line-item in cost containment efforts, there is an extremely robust academic literature finding that use of medicines can help save money on other health care services, especially hospitalizations and emergency department care. For instance:

- Every additional dollar spent on medicines for adherent patients with congestive heart failure, high blood pressure, diabetes or high cholesterol generates $3 to $10 dollars in savings on emergency room visits and inpatient hospitalizations.[xxx]

- Improving adherence to diabetes medicines could prevent 341,000 hospitalizations and 699,000 emergency department visits each year, resulting in annual savings of almost $5 billion.[xxxi]

- Greater adherence to statins could reduce total health care spending by more than $3 billion annually by reducing avoidable cardiovascular disease-related hospitalizations.[xxxii]

The opportunity for better health and savings on chronic illnesses through appropriate use of medicines is described by Harvard researcher Will Shrank and colleagues:

> [P]atients frequently are not prescribed essential chronic medications and frequently fail to adhere to them when they are prescribed; both of these issues have major consequences for public health. A national chart-based review of the quality of care in the United States indicated that patients receive essential chronic medication therapy only about half the time…Numerous other studies have shown that patients with chronic conditions such as coronary artery disease, hypertension, diabetes and hypercholesterolemia only adhere to 50% to 60% of medications as prescribed despite conclusive evidence that medication therapy can substantially improve life expectancy and quality of life. Medication nonadherence alone is estimated to increase healthcare costs by more than $170 billion annually in the United States. Efforts to stimulate better prescribing of and adherence to essential medications will increase value by improving population health, averting costly emergency department visits and hospitalizations, and improving quality of life and productivity.[xxxiii]

**Creation of Medicare Part D**

While medicines play a central role in today's health care system, prior to 2006 there was no outpatient prescription drug benefit through Medicare. Before Part D, about 30% of Medicare beneficiaries lacked any drug coverage[xxxiv]and many more had very limited coverage. There was widespread recognition by Members of Congress, the Administration, and advocates that the

absence of a central part of modern medical treatment from Medicare coverage was resulting in poor health outcomes that could be avoided[xxxv]and financial strain on beneficiaries (resulting from both the lack of prescription drug coverage and the lack of negotiated discounts for those without coverage). As a result, after many years of bipartisan efforts, Congress enacted legislation adding a prescription drug benefit to Medicare in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

The Part D program at the heart of MMA was structured to provide Medicare beneficiaries access to medicines through a choice among private plan offerings operating under a set of program standards with government oversight. At the time of its development, there was some skepticism about many aspects of the program design, including questions about whether private plans would participate, whether beneficiaries would choose to enroll in the benefit or be satisfied if they did, whether premiums would be affordable, whether costs would be contained, and whether better use of medicines would yield savings on other health care costs. The program's track record – nearly ten years after enactment – answers these questions. The vast majority of eligible Medicare beneficiaries did enroll in Part D. Private plan participation in the program has always been robust. Beneficiaries have consistently reported high satisfaction with Part D. The program has contained premiums and overall costs far below original estimates. And Medicare coverage for prescription drugs has produced savings in other parts of the Medicare program.

*Part D Plan Participation*

A guiding principle in designing Part D was that beneficiaries should have choice among plans, to find one that meets their individual cost and coverage needs. Initial concerns that private plans would not serve some or even perhaps any areas of the country led policymakers to incorporate in the law government-run fallback drug plans that would be established if an insufficient number of plans stepped forward. However, plan participation has been robust and the government fallback plans have never been implemented. Today over 35 million people have drug benefits through Medicare,[xxxvi] and beneficiaries in every region have at least 23 plans from which to choose.[xxxvii]

*Beneficiary Experience with Part D*

From the beneficiary perspective, Part D has made premiums and medicines affordable, and has improved access and utilization, leading to better health outcomes. Given this, it is not surprising that 94% of Part D enrollees report that they are satisfied with their drug coverage and 95% are confident that the level of coverage meets their needs.[xxxviii]

By the end of 2006, over half of previously uninsured beneficiaries enrolled in Part D.[xxxix] While not all eligible beneficiaries enrolled, the take-up rate was high and well-above that typically experienced in voluntary programs. Those who did enroll had greater health needs than those who did not.[xl]

Beneficiaries who previously did not have drug coverage realized a large reduction in out-of-pocket (OOP) spending on medicines, because they gained access to insurance plus plan-negotiated discounts. This reduction in beneficiary OOP cost improved access to and utilization of recommended medicines among beneficiaries, particularly the newly insured. For example, a study supported by PhRMA found that the share of beneficiaries reporting difficulty paying for prescriptions dropped by two-thirds among low-income subsidy (LIS) beneficiaries -- from almost 29.7% reporting difficulty in 2005 to 9.5% in 2007. Similarly, among non-LIS beneficiaries who were previously uninsured, such difficulty dropped by about half (21.3% to 10%).[xli] This data predates the establishment of coverage gap discounts.

Average beneficiary premiums have been lower than projected in each year of the program and have remained virtually flat over the last three years at $30 per month.[xlii] Notably, while the parameters of basic coverage for Part D are defined in law, plans are permitted to vary the benefit offerings so long as the plan they offer is equal in value to the defined standard and certain additional criteria are met. Allowing such variation has benefitted enrollees. Today, only 4% of beneficiaries have chosen Part D plans whose coverage parameters match those in statutorily defined standard coverage; the rest have chosen an alternative design.[xliii]

There is still much room to improve utilization patterns, which would yield better health outcomes and additional savings – but Part D has been a large step forward.

*Part D Cost Containment*

Part D has far lower total costs than originally projected and there have been continuing large reductions in projected costs up to the present. According to the latest CBO data, Part D is on a track to cost $348 billion (45%) less than projected for the initial 2004-2013 forecast period.[xliv] According to CBO figures, actual spending for Part D in 2012 – the latest year for which actual spending is available – was $55 billion. This is 55% lower than the initial 2004 baseline spending forecast for that year. Additionally, CMS announced earlier this spring that Part D's per capita costs would rise only 1.83% for 2013, the lowest growth rate in the history of the program.[xlv]

While it has been widely reported that actual costs for the Part D program today are far below initial forecasts, less well known but equally important is the fact that Part D spending forecasts have continued to fall up to the present as the program has gained a longer track record. For example, CBO data shows that actual spending for 2012 was 20% lower than the forecast made just two years prior, in 2010, when significant legislative changes were made to the program.[xlvi] Notably, CBO has reduced its 10-year projection for Part D spending by over $100 billion in each of the last three years.[xlvii] Given that there is extensive operational experience with the program, these reductions are clearly unrelated to the uncertainties underlying the initial forecast but instead relate to the continued pattern of low per capita growth, which has been lower than predicted year after year.

The size of the reduction in predicted spending for Medicare Part D has had a dramatic impact on CBO's predicted spending for all of Medicare. This is even more noteworthy given that Part D accounts for only 10% of total Medicare spending in 2012[xlviii] (this includes brand and generic ingredient cost, health plan cost, and pharmacy cost). In releasing its annual Budget and Economic Outlook report in February this year, CBO noted that "the largest downward revision in the current [Medicare] baseline is for spending for Medicare's Part D (prescription drugs)."[xlix] CBO's current prediction for total Medicare spending in 2013 is now 9% lower than initially projected in 2004, and the reduction in Part D spending is larger than this total reduction. While predicted spending for the rest of Medicare has increased relative to the forecast made in 2004, CBO's Part D spending projections have fallen by 54% over that period.[l]

*Better Use of Medicines Leads to Savings on other Medicare Costs*

At the time Part D was being developed, CBO expressly rejected calculating any savings in other parts of Medicare based on better access to medicines.[li] Since that time, a significant and growing body of research has developed showing that the use of prescribed medicines generates offsetting savings through reduced use of other medical services in the Medicare program. This body of evidence has profound implications for Medicare.

As the evidence of cost offsets from medicines has mounted and as more seniors and disabled Americans have gained better access to prescription coverage through Part D, in November of 2012 CBO announced a change to its cost estimating methodology to reflect "a substantial body of evidence" showing that increases in prescription drug use lead to offsetting reductions in spending for other Medicare medical services.[lii] Among the research CBO cited was an article published in the *Journal of the American Medical Association* finding that implementation of the Medicare prescription drug program was followed by a $1,200 average decrease in nondrug medical spending in both 2006 and 2007 among those who previously had limited drug coverage.[liii] Other researchers have associated this reduction in non-drug spending with achieving approximately $13.4 billion in overall savings during the first full year of Part D.[liv] CBO also cited a study by Harvard researchers, with support from PhRMA, showing that introduction of Medicare Part D significantly reduced the probability of hospitalization for eight conditions, leading to 4% fewer hospital admissions, or an estimated 77,000 fewer annual admissions nationally.[lv]

Just as the evidence has developed over time to support the consensus view that that medicines yield offsetting savings on other health care services, further development of the evidence will likely yield recognition of even larger savings than credited today. In its November report, CBO acknowledges that literature specific to a range of conditions shows medicines yielding larger offsetting savings than now built into CBO rules.[lvi] Preliminary findings from research in development supported by PhRMA suggests that the magnitude of offsetting savings for patients

suffering from congestive heart failure, diabetes and several other conditions may be three to six times higher than the population average reported by CBO. It will be important to closely monitor the development of the evidence base in this area.

**Competition Has Played a Central Role in Part D's Success**

Competitive forces at work within Part D's structure have played a key role in achieving the program's favorable outcomes, including incentives for plans seeking to obtain enrollment in a consumer choice environment, negotiated drug prices, and beneficiary choice among plans. The result has been a strong record of affordability outlined above and, on average, broader beneficiary access to medicines as compared to other public programs. For instance, Part D does not have arbitrary limits on the number of prescriptions covered per month, a feature that can be found in a number of state Medicaid programs. Additionally, as discussed further below, Part D plans generally have broader choice of medicines than is available in the Department of Veterans' Affairs (VA) drug benefit.

Many outside observers have also recognized the positive impact of competition within Part D. Former CBO Director Peter Orszag said, "[T]he bids are coming in and pricing is coming in better than anticipated, and that is likely a reflection of the competition that's occurring in the private market."[lvii] In announcing a Part D premium decrease for 2012, former Acting CMS Administrator Dr. Donald Berwick stated that "a competitive market and good competition among Part D plans" have played a critical role in controlling program costs.[lviii]

The competitive features of the Part D market clearly drive savings along with access. In fact, Part D plans provide more robust access than in programs like the VA or that would be provided under alternative approaches. CMS' standards set under the legislation creating Part D play a role in striking a balance between access and affordability, which will always be a dynamic issue within the program. CMS must remain diligent in monitoring the program to help sustain that balance.

*Negotiated Prices within Part D*

Robust negotiation of drug prices is one factor driving lower spending figures in Part D. Under current law and practice, private insurers and pharmacy benefit managers negotiate significant discounts and rebates on drugs dispensed to enrollees in their Part D plans and pass these savings on to beneficiaries and the Part D program. Evidence of such savings comes from the Government Accountability Office (GAO), which reported that Part D plans lowered costs for beneficiaries, "through their ability to negotiate prices with drug manufacturers and pharmacies … Sponsors must report the price concession amounts to CMS and pass price concessions onto beneficiaries and the program through lower cost sharing, lower drug prices, or lower premiums."[lix]

Some of Part D's plan sponsors and their pharmacy benefit managers (PBMs) represent total patient populations of 40-50 million individuals, and also negotiate on behalf of private employers and the Federal Employee Health Benefit Program (FEHBP).[lx] Just as in the commercial sector, these Part D plans negotiate to capture the largest possible discounts and rebates by using cost sharing and utilization management tools to steer patients to preferred medicines. CBO has found that Part D plans "have secured rebates somewhat larger than the average rebates observed in commercial health plans."[lxi] The Medicare Trustees note that "many brand-name prescription drugs carry substantial rebates, often as much as 20-30 percent."[lxii] Analysis of Medicare Trustee data shows that negotiated rebates have increased in each year of the program, repeatedly exceeding projected levels.[lxiii]

Repeated increases in the reported average levels of negotiated rebates in Part D are a tangible example of competition at work. The statutory provisions concerning pass-through of these privately negotiated rebates, and the competition among part D plans to attract enrollees, translate into tangible savings for Medicare beneficiaries. CMS recently announced that for the 2014 plan year, "due to decreases in the cost of the Medicare prescription drug program," the standard Part D prescription drug benefit will have lower co-payments and a lower deductible than in 2013.[lxiv]

*Powerful Incentives for Cost Control Have Driven Rapid Take-up of Generics*

Some observers have suggested that most of Part D's cost containment success is attributable to the "patent cliff" – an increase in generic use that happens when innovator medicines' patents expire. These observers argue that the similarity between drug spending trends inside and outside of Part D suggest no particular benefit from competition in Part D. But this argument misses several key points.

First, the timing and scale of the patent cliff has been well-known for many years, yet the 10-year cost projections for Part D continue to decline sharply – as previously mentioned, by over $100 billion in each of the past three years.[lxv]

Second, Part D was expressly designed to leverage the competitive tools already built into and widely used in the commercial marketplace, with plans and PBMs operating in a national market and highly sophisticated at purchasing drugs using plan design and formulary tools to negotiate discounts and rebates from brand manufacturers and drive high generic use rates among beneficiaries. Thus, Part D trends that are broadly similar to those in the commercial market reflect the competitive forces in the commercial sector and built into the Part D model.

Third, as discussed above, generics are a part of the competitive landscape in the U.S. market, representing a stage of the prescription medicine lifecycle. The U.S. market maximizes savings from use of generics, which is possible only because that drug was developed through the work

and investment of an innovator company. Generic drugs now account for 84% of all prescriptions filled in the U.S.,[lxvi] a higher rate than in many other developed countries. Additionally, while the competitive U.S. market operates to maximize savings from generics the 30 most commonly prescribed generic drugs are, on average, priced 96% higher outside the U.S.[lxvii] High rates of generic use are an inherent characteristic of the competitive market that achieves savings while allowing reallocation of resources to medical advances, not a separate, independent force.

According to data from IMS Health, the share of generic drugs dispensed in Part D has grown by 20 percentage points since the beginning of the program. Generic use in Part D is expected to continue to grow in future years.[lxviii]

Reflecting the prescription drug lifecycle that starts with innovation, a study conducted by IMS Health and a leading economist at the Massachusetts Institute of Technology, and supported by PhRMA, reported that the average daily cost of therapy for the ten most used therapeutic classes at the start of Part D declined by a third between 2006 and 2010, from $1.50 to $1.00; the average daily cost of therapy is projected to drop further to $0.65 by the end of 2015.[lxix]

*Choice of Plans Promotes Competition and Cost Savings*

Part D provides beneficiaries choice among plans, which promotes plan competition for enrollment and allows beneficiaries to select a plan that meets their individual cost and coverage needs. Some have questioned whether beneficiaries can make good choices among plans. Although there will always be opportunities to improve the match between a beneficiary's needs and the plan they choose, there are strong indications that beneficiaries have done a good job at navigating the choices available to them.

At the program's inception, a study commissioned by PhRMA found that in both 2006 and 2007 a very large majority of beneficiaries chose plans that combined lower-than-average premiums, and a broad choice of medicines.[lxx] More recently, MedPAC reported that over 13% of Part D enrollees switched plans in 2010 and 2011, more than double the rate reported at the outset of the program.[lxxi] Other new research finds that Part D enrollees who switched plans reduced their average annual out-of-pocket costs by almost $300,[lxxii] with researchers noting, "[o]ur results add to the accumulating evidence that Part D represents a successful implementation of a market-based approach to deliver a large-scale entitlement program."[lxxiii]

**Effective Negotiation Takes Place Today in Part D**

There is a widely held misperception that Part D bars negotiation of drug prices. That view is wrong. As already discussed, robust negotiation by large, powerful purchasers with many tools at their disposal and incentives to achieve savings is at the heart of Part D.

Claims that Part D prohibits negotiation misread the law's "noninterference" clause.[lxxiv] This language, which had origins in the Clinton Administration's Medicare prescription drug proposal and was later adopted in the legislative proposals advanced by both Democrats and Republicans before Part D was enacted, clearly provides *for* negotiation rather than barring negotiation. In fact, its express purpose is "to promote competition under [Part D]."[lxxv] However, the noninterference clause prohibits the *government* from "interfering" in the negotiations among Part D sponsors, pharmacies, and drug manufacturers, and from establishing a particular formulary for the program. Thus, with explicit safeguards in the law to protect negotiations, it is clear that active negotiations were at the heart of Part D's design. The real question about "negotiation" is not whether it should happen but *who* should negotiate.

Private plans and their PBMs negotiate price concessions with manufacturers and set formularies according to standards enforced by CMS (these standards allow for a range of outcomes rather than forcing uniformity in benefits and formularies). These sponsors and PBMs have long experience and deep expertise in negotiating with manufacturers and they bring to negotiations the purchasing clout of total patient populations of 40-50 million individuals. They also have the incentives and tools to drive hard bargains, and the expertise and infrastructure needed to purchase medicines and ensure the benefit includes appropriate medicines, including Pharmacy and Therapeutics (P&T) committees and other clinical experts.

The government does not match the experience, expertise, clinical knowledge and infrastructure that an ExpressScripts or UnitedHealthcare brings to the negotiating table,[lxxvi] because these private purchasers participating in Medicare also purchase medicines on behalf of tens of millions of consumers in the other parts of the health care marketplace, such as employer-sponsored insurance or FEHBP. Further, these private purchasers negotiate in a competitive market that gives Part D beneficiaries choices to align their needs with a plan. Those who suggest that the Secretary of Health and Human Services would be better positioned to negotiate on behalf of all Medicare beneficiaries don't account for these many other important factors that are foundational to the design of the Part D benefit.

For Secretarial negotiation to achieve larger savings than those achieved by Part D plans (with their strong record of cost containment), the Secretary would be expected to restrict access to medicines more than in today's program. The non-partisan CBO has consistently stated[lxxvii] that striking noninterference "would have a negligible effect on federal spending because … the Secretary would be unable to negotiate prices across the broad range of covered Part D drugs that are more favorable than those obtained by Part D plans under current law." To negotiate prices lower than those already achieved through negotiation between Part D plans and manufacturers, CBO states the government would need to impose additional access or coverage restrictions on Part D medicines, noting, "…the negotiating lever that's used to lower drug prices is the threat of not allowing that drug to be prescribed or putting limitations on its being prescribed within that drug plan."[lxxviii] Thus, the most likely outcome would be a one-size-fits-all formulary and benefit

structure, since the Secretary would presumably be negotiating on behalf of all Medicare beneficiaries and negotiation typically is centered on formulary placement and tiering. It is difficult to imagine that the Secretary could or would negotiate for the unique characteristics of each plan and formulary, or that the Secretary could appropriately engage in such commercially sensitive decisions for plans that compete with one another and that are regulated by the Secretary.

**VA Model Would Not be Sustainable for Medicare**

Some critics of the Part D program argue that drug prices should be "negotiated" for Part D as they are for the VA drug benefit. But proposals to use the VA as a model for Part D do not account for how the VA system works, and as a result underestimate the impact that would come from such a sweeping change. First, the VA prices are based on a statutory government price control formula. As discussed below, government price controls would damage the biopharmaceutical research enterprise that patients and policymakers alike count on to produce medical advances.

Second, VA operates a single national formulary with a limited range of available medicines, rather than giving veterans a choice among plan formularies as is the case in Part D. Moreover, this single VA formulary provides much more restrictive access to medicines than is typical in Part D. In a 2011 analysis by the Lewin Group for PhRMA, the most popular Part D plans covered 93% of the most routinely prescribed drugs for seniors, but only 67% of these drugs were covered by the VA formulary.[lxxix] Notably, a VA sponsored survey reports that about 40% of veterans supplement their VA coverage with Part D or private insurance,[lxxx] documenting that when VA beneficiaries have a choice, a majority prefer not to be limited to just the VA benefit.

Further, the VA delivers care through a closed health system, while Medicare beneficiaries rely on community physicians. When VA experimented with allowing veterans to use community physicians, up to 42% of all prescriptions prescribed were for medicines not on the VA formulary. Even after VA spent 20 weeks working to switch these prescriptions to on-formulary medicines, an average of 27% remained off formulary.[lxxxi] In sum, imposing the VA system on tens of millions of Medicare beneficiaries, most of whom would not have the option of another prescription drug plan, would have broad implications for access to care. For these reasons, the share of VA enrollees who plan to use VA services primarily for prescriptions in the future is steadily declining, and fell from 17% in 2005 to 8% in 2011.[lxxxii]

Finally, VA covers a relatively small population and as discussed above frequently does not serve as its enrollees' sole source of prescription drug coverage. Part D's enrollment is more than three times larger, and as a Yale economist has indicated,[lxxxiii] low pricing levels sustained via price controls for smaller programs cannot be expected to produce the same prices in Medicare. A restrictive, closed system designed for a very specific, small population does not translate easily to the diverse needs of over 35 million seniors and disabled beneficiaries.

**Applying Medicaid's Price Controls to Part D Would Not Return to a Prior Status Quo and Would Disrupt the Competitive Dynamics Responsible for the Program's Success**

Some policymakers have called for applying Medicaid price controls to medicines dispensed to recipients of the LIS in Medicare Part D. This policy would represent the first time that Medicaid payment rates would be mandated for the provision of Medicare services, establishing a different payment rate for a Medicare service based on a beneficiary's income level.

Policymakers advocating for this new policy often base their position on the fact that dual eligibles obtained their prescription drug coverage through Medicaid prior to implementation of Part D in 2006. Essentially, they argue that imposing Medicaid's price controls in Medicare would be a return to the pre-Part D status quo. However, this does not accurately describe the proposal or its likely impact.

First, prescription drug coverage for approximately six million dual eligible beneficiaries was intentionally transferred from Medicaid to Medicare by the MMA, a move that had the strong support of beneficiary advocates.[lxxxiv] At the same time, nearly twice that number (11 million) of individuals gained comprehensive drug coverage through Part D.[lxxxv] By gaining coverage, these individuals went from purchasing medicines at retail prices to benefiting from discounts and rebates from manufacturers that are negotiated by large, powerful purchasers. Part D also strengthened the negotiating power of payers by greatly increasing the number of covered lives, introduced the specialty tier that is now common in the insurance marketplace, and likely increased generic use beyond what it otherwise would have been. CMS reported in Part D's first year that many Part D plans increased generic use faster than the market as a whole.[lxxxvi] In sum, at its inception, Part D had many moving parts; focusing on one to the exclusion of all others is not a good basis for judging impact or making policy.

Second, these proposals would extend Medicaid price controls far beyond the population ever eligible for Medicaid benefits by applying to drugs dispensed to millions of additional Medicare beneficiaries who receive the Part D LIS but who are not and never were eligible for Medicaid drug benefits. The most recent Medicare Trustees report estimated that in 2012, Part D would have about 6.9 million dual eligibles, and 4.2 million non-dual eligible LIS enrollees.[lxxxvii] Thus, this policy would extend Medicaid price controls to a population of LIS recipients that is 160% of the size of the dual eligible population alone.

Third, both the Medicaid and Part D programs have gone through changes since 2006 that further distance today's proposals from the pre-Part D status quo. For example, in 2006, the statutorily required minimum rebate percentage on brand prescription drugs in Medicaid was 15.1 % of the drug's average manufacturer price (AMP). Subsequent legislation has raised the minimum mandatory rebate to 23.1 % of AMP, and this is the minimum rebate amount that is assumed in current proposals. Thus, current proposals would apply a much higher rebate percentage in Part D than ever applied to full-benefit dual eligibles when they previously received drug coverage

under Medicaid. The effects of taking a Medicaid policy enacted in 2010 and imposing it on Medicare Part D today would not be a return to the status quo of 2006.

Moreover, current rebate proposals do not account for the tens of billions of dollars in new discounts and fees that brand manufacturers pay. For example, biopharmaceutical manufacturers are now required to pay a 50% discount on all brand drugs dispensed to enrollees who are in the Part D coverage gap[lxxxviii] and to pay new fees into the Medicare program.[lxxxix] Furthermore, Medicaid price controls for prescription medicines were extended to tens of millions of additional individuals in Medicaid managed care. Altogether, analysts estimate the biopharmaceutical sector will pay more than $100 billion over ten years through provisions of the Affordable Care Act.[xc] These policies were not in place in 2003 when the MMA was signed into law or in 2006 when Part D was implemented, making any claim that imposing price controls is a return to the pre-Part D status quo incorrect.

To summarize, current proposals fail to account for both the many changes made by the MMA creating Part D and significant statutory changes in Medicaid and Part D since 2006, and would greatly expand the reach of Medicaid price controls to individuals who are not eligible for Medicaid benefits. There is not a justification for imposing Medicaid price controls on a Part D program that has achieved a strong record of cost containment, beneficiary satisfaction, and improved health outcomes.

*Adverse Impact of Medicaid Price Controls on Part D and Beneficiaries*

Part D's competitive structure already includes substantial negotiated discounts and rebates, and Part D plans have strong incentives within the current framework to reduce costs and appropriately manage drug spending. Layering market-distorting government price controls on top of a program that was designed to operate – and successfully does so – on a model employing negotiated discounts would not be a small or modest adjustment. Rather, it would undermine the program's balance of competitive forces and effectively shift to a reliance on traditional government-imposed line item price controls, despite the strong successes achieved for beneficiaries and taxpayers by the program's competitive structure.

Unlike the market-based rebates currently negotiated and passed through to beneficiaries in the form of lower premiums, deductibles, and cost sharing, mandatory government rebates in Part D would not return savings to Medicare beneficiaries. CBO has recognized that legislation imposing this type of price control in Medicare Part D could contribute to an increase in beneficiary premiums.[xci] Additionally, a former CBO director, as well as a Chief Actuary of CMS and a former senior CBO analyst have jointly cautioned that imposing Medicaid rebates in Part D would undermine the competitive dynamics in Part D and lead to significant market

distortions, potentially leading to higher premiums, reduced choices, higher copays, and more restrictive formularies.[xcii]

In a larger sense, requiring Medicaid-style rebates on drugs dispensed to Part D LIS beneficiaries would apply different pricing rules to low-income Medicare beneficiaries, since millions of Medicare beneficiaries in Parts A and B are either full-benefit dual eligibles or are receiving assistance from Medicaid in paying Medicare Part A or B cost-sharing or premiums. If Medicaid pricing became an accepted benchmark for Medicare, is unclear whether current Medicare benefits could be sustained.

**Preserving Incentives for R&D and Continued Medical Progress**

Proposals for new price controls in Part D could have a negative impact on R&D investment in the U.S. Today, the U.S. leads the world in drug discovery and development, and the potential for scientific breakthroughs in multiple disease areas has never been greater.

CBO has reported that a Medicaid-style rebate in Part D would reduce incentives for innovation "on products that would be expected to have significant Medicare sales"[xciii] and numerous reports by government agencies and academics have found that government price controls would harm future innovation and access to medicines.[xciv] For example, RAND researchers modeling the impact of price controls in the U.S. find they would negatively impact R&D investment needed for the development of new medicines and ultimately, health care outcomes. They conclude that "price regulations represent a risky policy strategy that may have a modest impact on lowering health costs in the United States, while having a longer-term cost of reducing development of new drugs that can reduce suffering and prolong life."[xcv]

Biopharma R&D can have a bright future as new scientific discoveries are opening up extraordinary possibilities for treating some of our most challenging and costly diseases. At the same time, it's important to recognize that analysts are increasingly citing falling returns on R&D in recent years, which may impact the industry's ability to bring these new medicines out of the pipeline. Notably, McKinsey & Company notes, "The return on investment for a typical biopharmaceutical portfolio today often will not even cover its cost of capital."[xcvi] Indicative of such challenges venture capital (VC) investment in emerging biopharmaceutical companies has been declining in recent years,[xcvii] and continues to be under severe pressure due to the escalating time, increased costs and uncertainty of new product development, combined with increasing coverage and payment pressures.[xcviii] New government price controls in Medicare would likely tip the scales resulting in further VC investment declines in the biopharma sector to less risky sectors.[xcix]

The biopharma sector is working hard to evolve in this new century to achieve new efficiencies and harness the full potential of the scientific and technological advancements now available to

us, so that the R&D process can be more productive. Likewise, the policies that govern how we work and how the health system works need to evolve. Part D was a part of that evolution in policy; applying government price controls would move backward. Only by evolving policy and science together will we achieve the biomedical advances that patients are counting on.

**Potential Areas for Improvement in Part D**

While the Part D program has been highly successful, there are opportunities to improve the program and ensure that all beneficiaries are receiving high quality care. One important opportunity for improvement relates to the Medication Therapy Management (MTM) Program, which was intended to optimize medication use among Part D beneficiaries. A recent CMS report evaluating the impact of MTM for beneficiaries with two costly chronic conditions, congestive heart failure and chronic obstructive pulmonary disease, found that the program was successful in increasing adherence and lowering hospitalization costs.[c] These findings are consistent with the research discussed above, showing that appropriate prescribing of medication therapy and better adherence improve quality and outcomes, while often reducing total costs and use of other more expensive health services.[ci]

Given MTM's potential to both improve outcomes and lower costs, it is important that the program reach the full range of beneficiaries who would benefit from active medication management. Part D plan sponsors tend to interpret the minimum eligibility criteria outlined by CMS in a way that misses many chronically ill beneficiaries who are at risk for underuse of medicines or poor adherence. CMS should consider specifying additional MTM eligibility criteria beyond drug costs, such as medication classes that treat chronic conditions, targeting beneficiaries that have high overall health spending rather than just high drug spending (which may require a waiver from the statutory eligibility provisions), or lowering the minimum Part D drug count threshold. We also encourage CMS to make its MTM data available to researchers, in order to determine which MTM program elements are most effective and to investigate ways to increase beneficiary participation in the program.

The MTM program also provides an opportunity to identify potential overuse, misuse or abuse within Part D and should be integrated with other efforts to identify problematic patterns of utilization, including drug-drug interactions, contraindicated medications, and medication errors. To further aid in identifying potential problems, we support CMS proposals to facilitate sharing of beneficiary-level utilization management data when beneficiaries change plans. Such data sharing could help plans identify potential safety risks and address plan shopping and doctor shopping that is driven by fraud and prescription abuse. It could also help avoid instances in which beneficiaries are required by a new plan sponsor to repeat a prior authorization process or step therapy program undergone previously, as this extra step can unnecessarily deny access to needed treatments. Separately, CMS could build on the Electronic Health Record (EHR)

incentive program to encourage participating physicians to complete annual medication reviews for their patients, and work to assure that EHRs incorporate medication fill data from PBMs and health plans.

Assuring that beneficiaries are able to make well-informed choices among plans is key to the success of Part D. As discussed earlier, MedPAC has recently reported that a larger share of beneficiaries are switching plans during annual open enrollment, and other research shows that switchers save money. There may be further opportunities to provide information to beneficiaries that would encourage them to shop when appropriate and help in identifying plans that would provide the best mix of access, premiums, and out of pocket costs.

Finally, improvements could be considered to ensure that the use of a specialty tier in Part D does not undermine access to needed medicines. In our past comments to CMS, we have recommended a more patient-centered approach that would allow patients to appeal specialty tier cost sharing by demonstrating a medical need for the specialty tier drug, as the rules allow for medicines on other tiers. CMS should also assure that a therapeutic alternative in the class be available to patients in a preferred tier before a medicine may be placed in the specialty tier. Taking these steps would ensure that patients needing specialty medicines do not face high barriers to accessing care.

**Conclusion**

I thank the Committee for convening this hearing to assess what we have learned in the 10 years since the Part D program was enacted. As I see it, a number of lessons have emerged.

First, the combination of private sector competition under government oversight of beneficiary protections has worked. The robust participation of plan sponsors and beneficiaries, combined with the continued reduction of Part D spending estimates and high enrollee satisfaction ratings all testify to this. Like any program, Part D could benefit from small adjustments and improvements; but on balance, the program has been high performing.

Second, beneficiaries value choice and have been able to make good decisions to address their cost and individual coverage needs. While some may need extra guidance and support to access what they need, Medicare beneficiaries are using the tools available to them to choose plans that work for them. It is not likely that a single plan could meet beneficiaries' varied needs as successfully as many plan offerings do.

Third, better use of medicines has a strong track record of improving health and generating cost savings in other parts of Medicare by reducing hospitalizations and emergency department visits.

Even with the improvements in utilization patterns brought about by Part D, there is much room for continued improvement. This is a rare opportunity in health care.

Fourth, Part D includes many effective cost containment features and incentives to provide good access to medicines. Government price controls and Secretarial "negotiation" are directly at odds with this system; injecting them would be a step backward that would undermine foundational aspects of the program.

Finally, we need to support continued biopharmaceutical innovation. Innovation is central to achieving widely agreed upon goals such as continuing to change the course of cancer, mental illnesses and neurodegenerative diseases, just as we've changed the course of HIV, hepatitis C and heart disease. Innovation can also support a more affordable health care system; as our society ages, Alzheimer's alone will cost Medicare and Medicaid close to $300 billion annually by 2030 without new medicines that delay its onset or slow its progression. Many biopharma research companies have been working at this, and there have been many highly publicized instances in which promising drugs that have been brought through the clinical trials have not achieved their goals and their development had to be cancelled. Companies continue to work on potential new treatments, just as they worked through scores of failures before developing the first approved medicine that cuts off the blood supply that cancer tumors use to grow.

With the right policy framework underpinning the innovative biopharma research enterprise, it will continue to make the future better than the past, with scientific advances yielding remarkable progress against disease along with economic growth and hope for patients.

Thank you for allowing me to testify today. I am happy to answer any questions you may have.

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